DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0049]

Agency Information Collection Activities; Proposed Collection; Comment Request; Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements establishing restrictions on the import, capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

Control of Communicable Diseases; African Rodents and Other Animals That May Carry the Monkeypox Virus—21 CFR 1240.63 (OMB Control Number 0910–0519)—Extension

Under 21 CFR 1240.63(a)(2)(ii), an individual must submit a written request to seek permission to capture, offer to capture, transportation, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and/or release into the environment any of the following animals:

- Prairie dogs (*Cynomys* sp.),
- African Tree squirrels (*Heliosciurus* sp.),
- Rope squirrels (*Funisciurus* sp.),
- African Dormice (*Graphiurus* sp.),
- Gambian giant pouched rats (*Cricetomys* sp.),
- Brush-tailed porcupines (*Atherurus* sp.),
- Striped mice (*Hybomys* sp.), or

Any other animal so prohibited by order of the Commissioner of Food and Drugs because of that animal's potential to transmit the monkeypox virus.

The request cannot seek written permission to sell, barter, or exchange, or offer to sell, barter, or exchange, as a pet, the animals listed previously or any animal covered by an order by the Commissioner of Food and Drugs.

The request must state the reasons why an exemption is needed, describe the animals involved, and explain why an exemption will not result in the spread of monkeypox within the United States.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

CFR Section	No. of Respondents	Annual Frequency per Response	Total No. of Responses	Hours per Response	Total Hours
21 CFR 1240.63(a)(2)(ii)	120	1	120	4	480
Total					480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on our experience to date with the interim final rule. To estimate the number of respondents, we examined the number of requests we have received since the June 11, 2003, order. FDA has received approximately 65 requests in a 7-month period, and most requests involved requests to move an animal from one location to another. As the agency cannot predict how the monkeypox outbreak will be resolved, FDA will tentatively estimate that 120 respondents would be affected. Furthermore, based on FDA's experience with requests submitted thus far, and the parties submitting those requests, the agency estimates that each respondent will need 4 hours to complete its request for an exemption. Therefore, the total reporting burden

under 21 CFR 1240.63(a)(2)(ii) will be 480 hours (120 respondents x 4 hours per response = 480 hours).

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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